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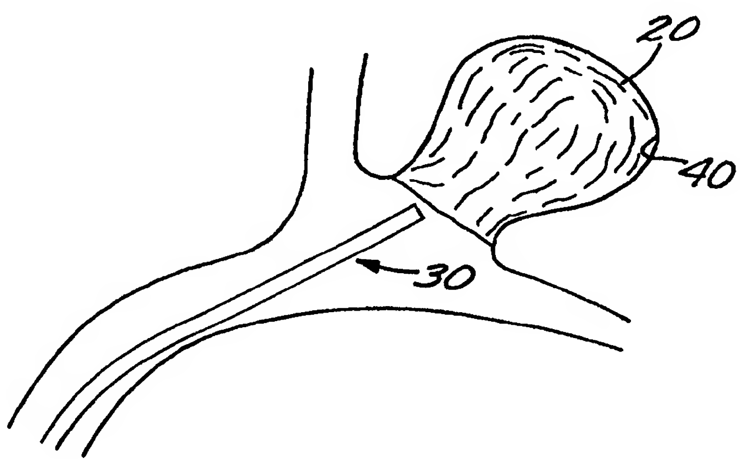
(54) Title: EXPANSIBLE IMPLANT FOR VASCULAR EMBOLIZATION AND METHOD OF MAKING THE SAME

(57) Abstract

A vascular implant formed of a compressible foam material has a compressed configuration from which it is expansible into a configuration substantially conforming to the shape and size of a vascular site to be embolized. Preferably, the implant is formed of a hydrophilic, macroporous foam material, having an initial configuration of a scaled–down model of the vascular site, from which it is compressible into the compressed configuration. The implant is made by scanning the vascular site to create a digitized scan data set; using the scan data set to create a three–dimensional digitized virtual model of the vascular site; using the virtual model to create a scaled–down physical mold of the vascular site; and using the mold to create a vascular implant in the form of a scaled–down model of the vascular site.



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EXPANSIBLE IMPLANT FOR VASCULAR EMBOLIZATION AND METHOD OF MAKING THE SAME

BACKGROUND OF THE INVENTION

The present invention relates to the field of methods and devices for the embolization of vascular aneurysms and similar vascular abnormalities. More specifically, the present invention relates to (a) an expansible vascular implant that is inserted into a vascular site such as an aneurysm to create an embolism therein; (b) a method of making the expansible implant; and (c) a method and an apparatus for embolizing a vascular site using the implant.

The embolization of blood vessels is desired in a number of clinical situations. For example, vascular embolization has been used to control vascular bleeding, to occlude the blood supply to tumors, and to occlude vascular aneurysms, particularly intracranial aneurysms. In recent years, vascular embolization for the treatment of aneurysms has received much attention. Several different treatment modalities have been employed in the prior art. U.S. Patent No. 4,819,637 - Dormandy, Jr. et al., for example, describes a vascular embolization system that employs a detachable balloon delivered to the aneurysm site by an intravascular catheter. The balloon is carried into the aneurysm at the tip of the catheter, and it is inflated inside the aneurysm with a solidifying fluid (typically a polymerizable resin or gel) to occlude the aneurysm. The balloon is then detached from the catheter by gentle traction on the catheter. While the balloon-type embolization device can provide an effective occlusion of many types of aneurysms, it is difficult to retrieve or move after the solidifying fluid sets, and it is difficult to visualize unless it is filled with a contrast material. Furthermore, there are risks of balloon rupture during inflation and of premature detachment of the balloon from the catheter.

Another approach is the direct injection of a liquid polymer embolic agent into the vascular site to be occluded. One type of liquid polymer used in the direct injection technique is a rapidly polymerizing liquid, such as a cyanoacrylate resin, particularly isobutyl cyanoacrylate, that is delivered to the target site as a liquid, and then is polymerized *in situ*. Alternatively, a liquid polymer that is precipitated at the target site from a carrier solution has been used. An example of this type of embolic agent is a cellulose acetate polymer mixed with bismuth trioxide and dissolved in dimethyl sulfoxide (DMSO). Another type is ethylene glycol copolymer dissolved in DMSO. On contact with blood, the DMSO diffuses out, and the polymer precipitates out and rapidly hardens into an embolic mass that conforms to the shape of the aneurysm. Other examples of materials used in this "direct injection" method are disclosed in the following U.S. Patents: 4,551,132 - Pásztor et al.; 4,795,741 - Leshchiner et al.; 5,525,334 - Ito et al.; and 5,580,568 - Greff et al.

The direct injection of liquid polymer embolic agents has proven difficult in practice. For example, migration of the polymeric material from the aneurysm and into the adjacent blood vessel has presented a problem. In addition, visualization of the embolization material requires that a contrasting agent be mixed with it, and selecting embolization materials and contrasting agents that are mutually compatible may result in performance compromises that are less than optimal. Furthermore, precise control of the deployment of the polymeric embolization material is difficult, leading to the risk of improper placement and/or premature solidification of the material. Moreover, once the embolization material is deployed and solidified, it is difficult to move or retrieve.

Another approach that has shown promise is the use of thrombogenic microcoils. These microcoils may be made of a biocompatible metal alloy (typically platinum and tungsten) or a suitable polymer. If made of metal, the

coil may be provided with Dacron fibers to increase thrombogenicity. The coil is deployed through a microcatheter to the vascular site. Examples of microcoils are disclosed in the following U.S. patents: 4,994,069 - Ritchart et al.; 5,133,731 - Butler et al.; 5,226,911 - Chee et al.; 5,312,415 - Palermo; 5,382,259 - Phelps et al.; 5,382,260 - Dormandy, Jr. et al.; 5,476,472 - Dormandy, Jr. et al.; 5,578,074 - Mirigian; 5,582,619 - Ken; 5,624,461 - Mariant; 5,645,558 - Horton; 5,658,308 - Snyder; and 5,718,711 - Berenstein et al.

The microcoil approach has met with some success in treating small aneurysms with narrow necks, but the coil must be tightly packed into the aneurysm to avoid shifting that can lead to recanalization. Microcoils have been less successful in the treatment of larger aneurysms, especially those with relatively wide necks. A disadvantage of microcoils is that they are not easily retrievable; if a coil migrates out of the aneurysm, a second procedure to retrieve it and move it back into place is necessary. Furthermore, complete packing of an aneurysm using microcoils can be difficult to achieve in practice.

A specific type of microcoil that has achieved a measure of success is the Guglielmi Detachable Coil ("GDC"). The GDC employs a platinum wire coil fixed to a stainless steel guidewire by a solder connection. After the coil is placed inside an aneurysm, an electrical current is applied to the guidewire, which heats sufficiently to melt the solder junction, thereby detaching the coil from the guidewire. The application of the current also creates a positive electrical charge on the coil, which attracts negatively-charged blood cells, platelets, and fibrinogen, thereby increasing the thrombogenicity of the coil. Several coils of different diameters and lengths can be packed into an aneurysm until the aneurysm is completely filled. The coils thus create and hold a thrombus within the aneurysm, inhibiting its displacement and its

fragmentation.

The advantages of the GDC procedure are the ability to withdraw and relocate the coil if it migrates from its desired location, and the enhanced ability to promote the formation of a stable thrombus within the aneurysm. Nevertheless, as in conventional microcoil techniques, the successful use of the GDC procedure has been substantially limited to small aneurysms with narrow necks.

Still another approach to the embolization of an abnormal vascular site is the injection into the site of a biocompatible hydrogel, such as poly (2-hydroxyethyl methacrylate) ("pHEMA" or "PHEMA"); or a polyvinyl alcohol foam ("PAF"). See, e.g., Horák et al., "Hydrogels in Endovascular Embolization. II. Clinical Use of Spherical Particles", *Biomaterials*, Vol. 7, pp. 467-470 (Nov., 1986); Rao et al., "Hydrolysed Microspheres from Cross-Linked Polymethyl Methacrylate", *J. Neuroradiol.*, Vol. 18, pp. 61-69 (1991); Latchaw et al., "Polyvinyl Foam Embolization of Vascular and Neoplastic Lesions of the Head, Neck, and Spine", *Radiology*, Vol. 131, pp. 669-679 (June, 1979). These materials are delivered as microparticles in a carrier fluid that is injected into the vascular site, a process that has proven difficult to control.

A further development has been the formulation of the hydrogel materials into a preformed implant or plug that is installed in the vascular site by means such as a microcatheter. See, e.g., U.S. Patent Nos. 5,258,042 - Mehta and 5,456,693 - Conston et al. These types of plugs or implants are primarily designed for obstructing blood flow through a tubular vessel or the neck of an aneurysm, and they are not easily adapted for precise implantation within a sack-shaped vascular structure, such as an aneurysm, so as to fill substantially the entire volume of the structure.

There has thus been a long-felt, but as yet unsatisfied need for an

aneurysm treatment device and method that can substantially fill aneurysms of a large range of sizes, configurations, and neck widths with a thrombogenic medium with a minimal risk of inadvertent aneurysm rupture or blood vessel wall damage. There has been a further need for such a method and device that also allow for the precise locational deployment of the medium, while also minimizing the potential for migration away from the target location. In addition, a method and device meeting these criteria should also be relatively easy to use in a clinical setting. Such ease of use, for example, should preferably include a provision for good visualization of the device during and after deployment in an aneurysm.

SUMMARY OF THE INVENTION

Broadly, a first aspect of the present invention is a device for occluding a vascular site, such as an aneurysm, comprising a conformal vascular implant, formed of an expansible material, that is compressible from an initial configuration for insertion into the vascular site by means such as a microcatheter while the implant is in a compressed configuration, and that is expansible *in situ* into an expanded configuration in which it substantially fills the vascular site, thereby to embolize the site, wherein the initial configuration of the implant is a scaled-down model of the vascular site.

In a preferred embodiment, the implant is made of a hydrophilic, macroporous, polymeric, hydrogel foam material, in particular a water-swellable foam matrix formed as a macroporous solid comprising a foam stabilizing agent and a polymer or copolymer of a free radical polymerizable hydrophilic olefin monomer cross-linked with up to about 10% by weight of a multiolefin-functional cross-linking agent. The material is modified, or contains additives, to make the implant visible by conventional imaging techniques.

Another aspect of the present invention is a method of manufacturing a

vascular implant, comprising the steps of: (a) imaging a vascular site by scanning the vascular site to create a digitized scan data set; (b) using the scan data set to create a three-dimensional digitized virtual model of the vascular site; and (c) forming a vascular implant device in the form of a physical model of the vascular site, using the virtual model, the implant being formed of a compressible and expansible biocompatible foam material. In a specific embodiment, the forming step (c) comprises the substeps of: (c)(1) using the virtual model to create a scaled-down, three-dimensional physical mold of the vascular site; and (c)(2) using the mold to create a vascular implant in the form of a scaled-down physical model of the vascular site.

In the preferred embodiment of the method of manufacturing the implant, the imaging step is performed with a scanning technique such as computer tomography (commonly called "CT" or "CAT"), magnetic resonance imaging (MRI), magnetic resonance angiography (MRA), or ultrasound. Commercially-available software, typically packaged with and employed by the scanning apparatus, reconstructs the scan data set created by the imaging into the three-dimensional digitized model of the vascular site. The digitized model is then translated, by commercially-available software, into a form that is useable in a commercially available CAD/CAM program to create the scaled-down physical mold by means of stereolithography. A suitable implant material, preferably a macroporous hydrogel foam material, is injected in a liquid or semiliquid state into the mold. Once solidified, the hydrogel foam material is removed from the mold as an implant in the form of a scaled-down physical model of the vascular site.

A third aspect of the present invention is a method for embolizing a vascular site, comprising the steps of: (a) passing a microcatheter intravascularly so that its distal end is in a vascular site; (b) providing a vascular implant in the form of a scaled-down physical model of the vascular

site, the implant being formed of a compressible and expansible biocompatible foam material; (c) compressing the implant into a compressed configuration dimensioned to pass through a microcatheter; (d) passing the implant, while it is in its compressed configuration, through the microcatheter so that the implant emerges from the distal end of the microcatheter into the vascular site; and (e) expanding the implant *in situ* substantially to fill the vascular site.

The apparatus employed in the embolization method comprises an elongate, flexible deployment element dimensioned to fit axially within an intravascular microcatheter; a filamentous implant retention element disposed axially through the deployment element from its proximal end to its distal end; and an implant device removably attached to the distal end of the retention element.

The implant device, in its preferred embodiment, is formed of a moldable, hydrophilically expansible, biocompatible foam material that has an initial configuration in the form of a scaled-down physical model of the vascular site, that is compressible into a compressed configuration that fits within the microcatheter, and that is hydrophilically expansible into an expanded configuration in which it is dimensioned substantially to conform to and fill the vascular site. Alternatively, the implant device may be formed of a non-hydrophilic foam material having an initial configuration that is substantially the same size and shape as the vascular site, and that restores itself to its initial configuration after it is released from its compressed configuration.

The retention element is preferably a flexible wire having a distal end configured to releasably engage the implant device while the implant device is in its compressed configuration, thus to retain the implant device within the distal end of the microcatheter while the distal end of the microcatheter is inserted into the vascular site. The wire is movable axially with the

deployment element in the distal direction to expose the implant from the distal end of the microcatheter, and is movable proximally with respect to the deployment element to urge the implant device against the distal end of the deployment element, thereby push the implant device off of the wire. Thus released into the vascular site, the implant device expands into an expanded configuration in which it substantially conforms to and fills the vascular site.

The present invention provides a number of significant advantages. Specifically, the present invention provides an effective vascular embolization implant that can be deployed within a vascular site with excellent locational control, and with a lower risk of vascular rupture, tissue damage, or migration than with prior art implant devices. Furthermore, the implant device, by being modelled on the actual vascular site in which it is to be implanted, effects a conformal fit within the site that promotes effective embolization, and yet its ability to be delivered to the site in a highly compressed configuration facilitates precise and highly controllable deployment with a microcatheter. In addition, the method of fabricating the implant device, by modeling it on each individual site, allows implant devices to be made that can effectively embolize vascular sites having a wide variety of sizes, configurations, and (in the particular case of aneurysms) neck widths. These and other advantages will be readily appreciated from the detailed description that follows.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a flow chart showing a method of manufacturing a vascular implant in accordance with a preferred embodiment of the manufacturing method aspect of the present invention;

Figure 2 is a perspective view of a vascular implant in accordance with a preferred embodiment of the vascular implant device aspect of the present invention, showing the implant in its initial configuration;

Figure 3 is an elevational view of the implant of Figure 2, showing the

implant in its compressed configuration;

Figure 4 is a perspective view of the implant of Figure 2, showing the implant in its expanded configuration;

Figure 5 is a cross-sectional view of an implanting apparatus employed in a method of embolizing a vascular site in accordance with a preferred embodiment of the embolizing method aspect of the present invention; and

Figures 6 through 10 are semischematic views showing the steps in a method of embolizing a vascular site (specifically, an aneurysm) in accordance with a preferred embodiment of the embolizing method aspect of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

The Method of Manufacturing a Vascular Implant. A first aspect of the present invention is a method of manufacturing a vascular implant device. The steps of a preferred embodiment of the manufacturing method are shown as a sequence of descriptive boxes in the flow chart of Figure 1.

The first step, shown in box 10 of Figure 1, is the step of creating an image of a vascular site, such as an aneurysm, in which an embolizing implant is to be installed. This imaging step is performed by scanning the site using any of several conventional imaging techniques, such as computer tomography, magnetic resonance imaging (MRI), magnetic resonance angiography (MRA), or ultrasound.

The result of the imaging step is a digitized scan data set that is stored in a computer memory, from which the data set is retrieved for operation of the next step: computerized reconstruction of a three-dimensional digitized virtual model of the vascular site (box 12 of Figure 1). This step of creating a three-dimensional digital model is typically performed by software designed for this purpose that is packaged with and employed by the imaging apparatus.

The digitized, three-dimensional virtual model is then translated into a form in which it can be employed in a commercially-available CAD/CAM program (box 14) which controls a stereolithography process (box 16) to create a mold for forming an implant device. The translation of the virtual model is performed by software that is commercially available, for example, from Cyberform International, Inc., of Richardson, Texas, and from Stratasys, Inc., of Minneapolis, Minnesota. The mold (not shown) is preferably scaled-down from the dimensions of the vascular site, with a scale of about 1:2 to about 1:6, with about 1:4 being preferred. Alternatively, the mold may be made "life size" (i.e., 1:1); that is, a full-size or nearly full-size replica of the vascular site. The mold is used in the fabrication of a vascular implant device by conventional molding techniques (box 18).

<u>The Implant Device</u>. A vascular implant device 20, in accordance with the present invention, is shown in Figure 2 as it appears in its uncompressed or precompressed initial configuration after withdrawal from the mold. Preferably, the implant device 20 is molded directly onto the distal end portion of an elongate, flexible, filamentous retention element, such as a retention wire 22, for purposes to be described below. The retention wire 22 preferably has a distal end that terminates in a knob 24 (Figure 5) for better retention of the implant device 20 thereon.

In the preferred embodiment, the implant device 20 is made of a biocompatible, macroporous, hydrophilic hydrogel foam material, in particular a water-swellable foam matrix formed as a macroporous solid comprising a foam stabilizing agent and a polymer or copolymer of a free radical polymerizable hydrophilic olefin monomer cross-linked with up to about 10% by weight of a multiolefin-functional cross-linking agent. A suitable material of this type is described in U.S. Patent No. 5,570,585 - Park et al., the disclosure of which is incorporated herein by reference. Another suitable

material is a porous hydrated polyvinyl alcohol foam (PAF) gel prepared from a polyvinyl alcohol solution in a mixed solvent consisting of water and a water-miscible organic solvent, as described, for example, in U.S. Patent No. 4,663,358 - Hyon et al., the disclosure of which is incorporated herein by reference. Still another suitable material is PHEMA, as discussed in the references cited above. See, e.g., Horák et al., *supra*, and Rao et al., *supra*. The foam material preferably has a void ratio of at least about 90%, and its hydrophilic properties are such that it has a water content of at least about 90% when fully hydrated.

In a preferred embodiment, the implant device 20, in its initial, precompressed configuration, will have the same configuration as the vascular site, but it will be smaller, by a factor of approximately two to approximately six. The material of the implant device 20, and its initial size, are selected so that the implant device 20 is swellable or expansible to approximately the size of the vascular site, primarily by the hydrophilic absorption of water molecules from blood plasma, and secondarily by the filling of its pores with blood. The result is an expanded configuration for the implant device 20, as shown in Figure 4, that is large enough substantially to fill the vascular site.

Alternatively, the implant 20 device can be molded so that in its initial, precompressed configuration, it is "life size", i.e., approximately the same size as the vascular site. In this case, the preferred material is a compressible, non-hydrophilic polymeric foam material, such as polyurethane. In actual clinical practice, a non-hydrophilic implant device 20 would advantageously be made slightly smaller than actual life size, to accommodate swelling due to the filling of the pores.

The foam material of the implant device 20, whether hydrophilic or non-hydrophilic, is advantageously modified, or contains additives, to make the implant 20 visible by conventional imaging techniques. For example, the

foam can be impregnated with a water-insoluble radiopaque material such as barium sulfate, as described by Thanoo et al., "Radiopaque Hydrogel Microspheres", *J. Microencapsulation*, Vol. 6, No. 2, pp. 233-244 (1989). Alternatively, the hydrogel monomers can be copolymerized with radiopaque materials, as described in Horák et al., "New Radiopaque PolyHEMA-Based Hydrogel Particles", *J. Biomedical Materials Research*, Vol. 34, pp. 183-188 (1997).

Whatever the material from which the implant device 20 is made, the implant device 20 must be compressible to a fraction of its initial size, preferably into a substantially cylindrical or lozenge-shaped configuration, as shown in Figure 3. Compression of the implant device 20 can be performed by squeezing it or crimping it with any suitable fixture or implement (not shown), and then "setting" it in its compressed configuration by heating and/or drying, as is well-known. The purpose for this compression will be explained below in connection with the method of using the implant device 20 to embolize a vascular site.

<u>The Method and Apparatus for Embolizing a Vascular Site</u>. The method of embolizing a vascular site using the implant device 20 is performed using an implanting apparatus 30, a preferred embodiment of which is shown in Figure 5. The implanting apparatus 30 comprises the retention element or wire 22, a microcatheter 32, and an elongate, flexible, hollow, tubular element 34 (preferably a coil) that functions as an implant deployment element, as will be described below. With the implant device 20 attached to the distal end of the retention wire 22, the proximal end of the retention wire 22 is inserted into the distal end of the implant deployment element 34 and threaded axially through the implant deployment element 34 until the proximal end of the implant device 20 seats against, or is closely adjacent to, the distal end of the implant deployment element 34. The implant deployment element 34 is

dimensioned for passing axially through the microcatheter 32. Thus, the implant deployment element 34, with the implant device 20 extending from its proximal end, may be inserted into the proximal end (not shown) of the microcatheter 32 and passed axially therethrough until the implant device 20 emerges from the distal end of the microcatheter 32, as shown in Figure 5.

The implant device 20, in its compressed configuration, has a maximum outside diameter that is less than the inside diameter of the microcatheter 32, so that the implant device 20 can be passed through the microcatheter 32. The implant device 20 is preferably compressed and "set", as described above, before it is inserted into the microcatheter 32.

Figures 6 through 10 illustrate the steps employed in the method of embolizing a vascular site 40 using the implant device 20. The vascular site 40 shown in the drawings is a typical aneurysm, but the invention is not limited to any particular type of vascular site to be embolized.

First, as shown in Figure 6, the microcatheter 32 is threaded intravascularly, by conventional means, until its distal end is situated within the vascular site 40. This threading operation is typically performed by first introducing a catheter guidewire (not shown) along the desired microcatheter path, and then feeding the microcatheter 32 over the catheter guidewire until the microcatheter 32 is positioned substantially as shown in Figure 6. The catheter guidewire is then removed.

The implant deployment element 34, with the implant device 20 extending from its distal end, is then passed through the microcatheter 32, as described above, until the implant device 20 emerges from the distal end of the microcatheter 32 into the vascular site 40, as shown in Figures 7 and 8. When inserting the implant device 20 into the microcatheter 32, a biocompatible non-aqueous fluid, such as polyethylene glycol, may be injected into the microcatheter 32 to prevent premature expansion of the implant device 20 due

to hydration, and to reduce friction with the interior of the microcatheter 32. The implant device 20 thus being exposed from the microcatheter 32 into the interior of the vascular site 40, the pores of the implant device 20 begin to absorb aqueous fluid from the blood within the vascular site 40 to release its "set", allowing it to begin assuming its expanded configuration, as shown in Figure 9. Then, if the implant device 20 is of a hydrophilic material, it continues to expand due to hydrophilic hydration of the implant material, as well as from the filling of its pores with blood. If the implant device 20 is of a non-hydrophilic material, its expansion is due to the latter mechanism only.

Finally, when the expansion of the implant device 20 is well underway (and not necessarily when it is completed), the retention wire 22 is pulled proximally with respect to the implant deployment element 34, causing the implant device to be pushed off the end of the installation wire 22 by means of the pressure applied to it by the distal end of the implant deployment element 34. The implant device 20, now free of the implanting apparatus 30, as shown in Figure 10, may continue to expand until it substantially fills the vascular site 40. The implanting apparatus 30 is then removed, leaving the implant device 20 in place to embolize the vascular site 40.

While a preferred embodiment of the invention has been described above, a number of variations and modifications may suggest themselves to those skilled in the pertinent arts. For example, instead of custom-fabricating the implant device for each patient, implant devices in a variety of "standard" sizes and shapes may be made, and a particular implant device then selected for a patient based on the imaging of the vascular site. In this case, the fabrication method shown in Figure 1 would be modified by first creating a three-dimensional digital model for each standardized implant, (box 12), and then proceeding with the subsequent steps shown in boxes 14, 16, and 18. Imaging (box 10) would be performed as an early step in the embolization

procedure, followed by the selection of one of the standardized implant devices. This and other variations and modifications are considered within the spirit and scope of the invention, as described in the claims that follow.

WHAT IS CLAIMED IS:

1. A vascular implant device for embolizing a vascular site, the device having a compressed configuration from which it is expansible into an expanded configuration substantially conforming to the shape and size of the vascular site.

2. The vascular implant device of Claim 1, wherein the implant device has an initial configuration in which it is in the form of a scaled-down model of the vascular site, and from which it is compressible into the compressed configuration.

3. The vascular implant device of Claim 2, wherein the device is formed of a hydrophilic foam material.

4. The vascular implant device of Claim 3, wherein the foam material is a macroporous hydrogel foam material.

5. The vascular implant device of Claim 1, wherein the implant device is compressible into its compressed configuration from its expanded configuration.

6. The vascular implant device of Claim 5, wherein the device is formed of a substantially non-hydrophilic polymeric foam material.

7. The vascular implant device of Claim 1, wherein the device is radiopaque.

8. A method of manufacturing a vascular implant device for embolizing a vascular site, comprising the steps of:

(a) imaging a vascular site by scanning the vascular site to create a digitized scan data set;

(b) creating a three-dimensional digitized virtual model of the vascular site using the scan data set; and

(c) forming a vascular implant device in the configuration of a physical model of the vascular site, using the virtual model, the implant being formed

from a compressible foam material.

9. The method of Claim 8, wherein the forming step comprises the steps of:

(c)(1) creating a three-dimensional physical mold of the vascular site using the virtual model; and

(c)(2) molding a vascular implant in the configuration of a physical model of the vascular site.

10. The method of Claim 9, wherein the physical mold created in the step of creating the physical mold is a scaled-down physical mold.

11. The method of Claim 10, wherein the implant molded in the molding step is in the form of a scaled-down physical model of the vascular site.

12. The method of Claim 8, wherein the imaging step is performed by a technique selected from the group consisting of computer tomography, magnetic resonance imaging, magnetic resonance angiography, and ultrasound.

13. The method of Claim 8, wherein the step of creating a virtual model is performed by a computer program.

14. The method of Claim 9, wherein the step of creating the mold is performed by a CAD/CAM program.

15. The method of Claim 14, wherein the step of creating the mold is performed by stereolithography controlled by the CAD/CAM program.

16. The method of Claim 11, wherein the compressible foam material includes a hydrophilically expansible foam material.

17. The method of Claim 16, wherein the foam material includes a macroporous hydrogel foam material.

18. The method of Claim 9, wherein physical mold created in the step of creating a physical mold is a substantially full size replica of the vascular

site.

19. The method of Claim 18, wherein the implant molded in the molding step is a substantially full size model of the vascular site.

20. The method of Claim 19, wherein the compressible foam material includes a substantially non-hydrophilic polymeric foam material.

21. A method of embolizing a vascular site, comprising the steps of:

(a) providing a vascular implant in the form of a physical model of the vascular site, the implant being formed of a moldable, compressible foam material;

(b) compressing the implant into a compressed configuration; (c) deploying the implant in a vascular site with a microcatheter, while the implant is in its compressed configuration; and

(d) expanding the implant *in situ* substantially to fill the vascular site.

22. The method of Claim 21, wherein the implant is in the form of a scaled-down model of the vascular site, and wherein the implant is formed of a hydrophilically-expansible foam material.

23. The method of Claim 22, wherein the expanding step is performed by the hydrophilic absorption of fluid by the implant.

24. The method of Claim 21, wherein the deploying step comprises the steps of:

(c)(1) inserting the distal end of the microcatheter into the vascular site;

(c)(2) passing the implant through the microcatheter, while the implant is in its compressed configuration, until the implant emerges from the distal end thereof into the vascular site; and

(c)(3) releasing the implant, while in its compressed configuration, from the distal end of the microcatheter.

25. Apparatus for embolizing a vascular site, comprising:

a microcatheter having a distal end and a proximal end;

a vascular implant device configured as a model of the vascular site and formed of a compressible foam material, the implant device having a compressed configuration dimensioned to pass through the microcatheter from the proximal end thereof and out of the distal end thereof;

a retention element contained within the microcatheter and having a distal end detachably connected to the implant device; and

a deployment element operably associated with the retention element and engageable against the implant device so as to separate the implant device from the retention element when the implant device has emerged from the distal end of the microcatheter.

26. The apparatus of Claim 25, wherein the deployment element is dimensioned to pass axially through the microcatheter from the proximal end to the distal end thereof, the deployment element having a distal end that is engageable against the implant device; and

wherein the retention element is movable with the deployment element when the deployment element is passed through the microcatheter, and is also movable between first and second positions relative to the distal end of the deployment element, whereby the implant device is displaced out of the distal end of the microcatheter when the deployment element is passed through the microcatheter, and whereby the implant device is separated from the retention element when the retention element is moved from the first position to the second position.

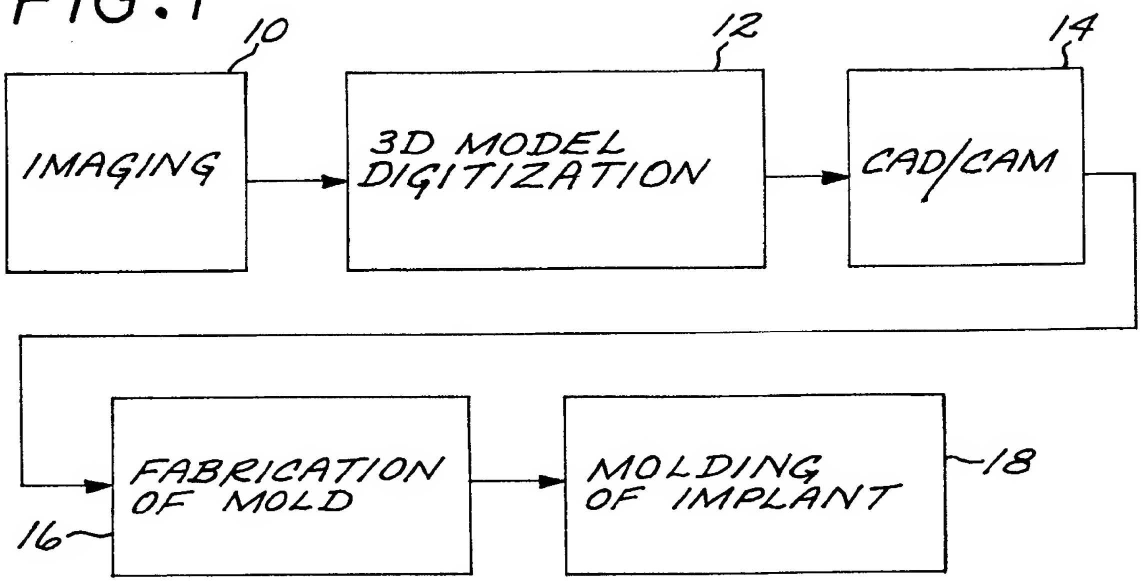
27. The apparatus of Claim 25, wherein the implant device is initially configured as a scaled-down model of the vascular site and has an expanded configuration in which its substantially conforms to the vascular site.

28. The apparatus of Claim 27, wherein the implant device is formed of a hydrophilic, macroporous, polymeric foam material.

29. The apparatus of Claim 25, wherein the deployment element comprises an elongate, flexible, tubular element.

30. The apparatus of Claim 29, wherein the retention element comprises an elongate, flexible, filamentous element disposed axially through the tubular element and movable with respect thereto between the first and second positions.

FIG. 1



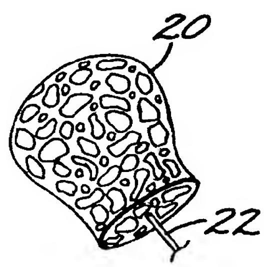


FIG. 2

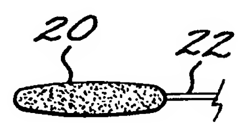


FIG. 3

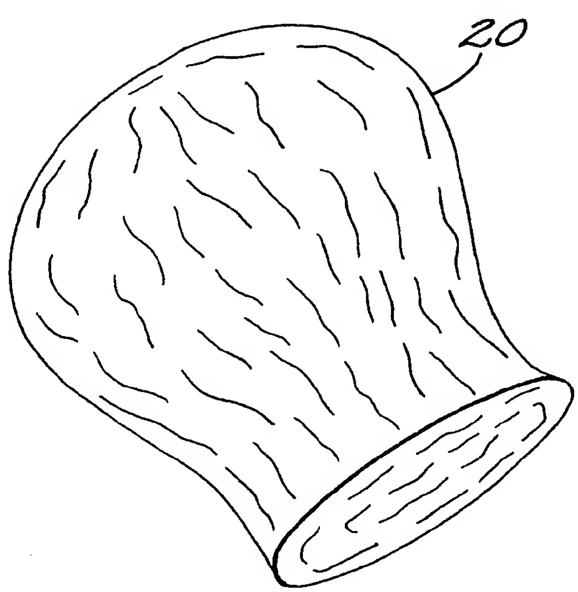


FIG. 4

FIG.5

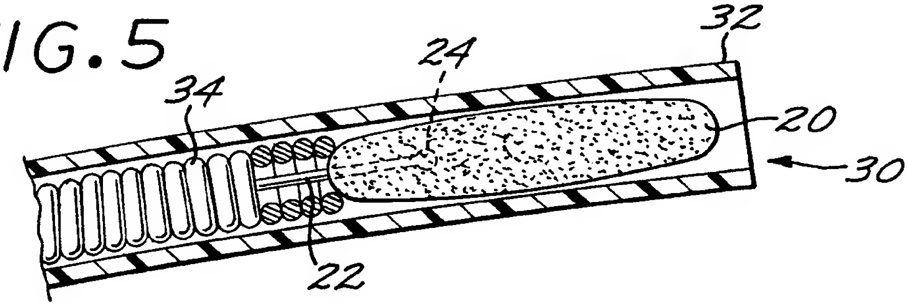


FIG.6

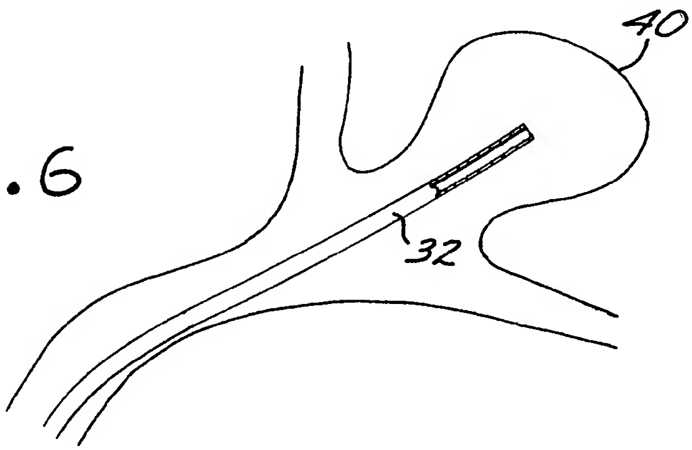


FIG.7

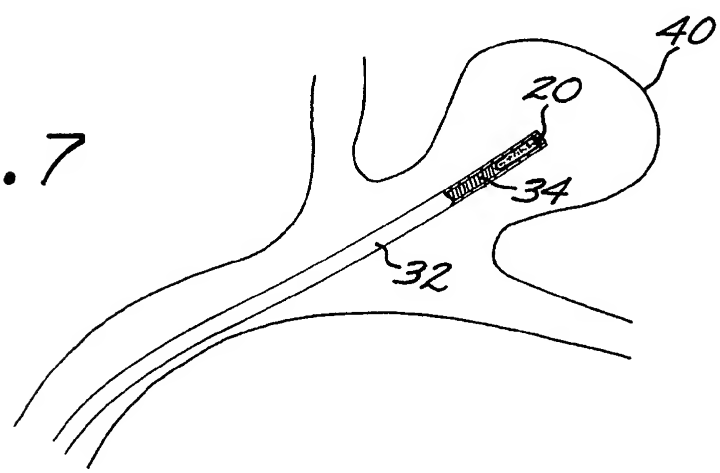


FIG. 8

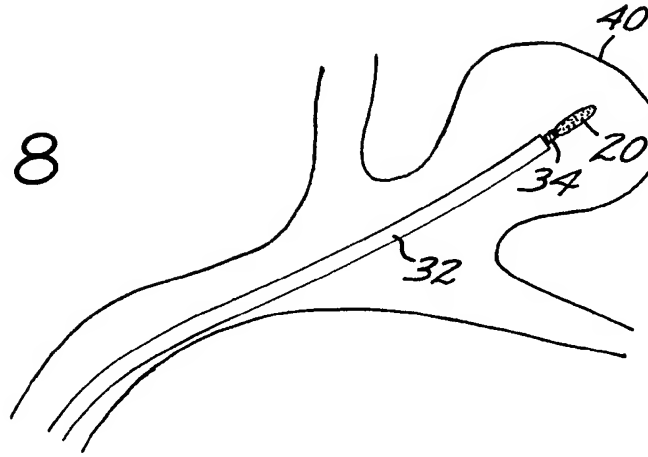


FIG. 9

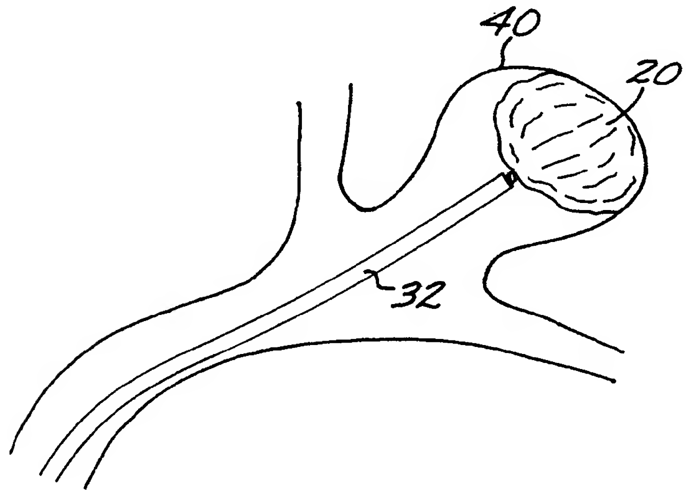
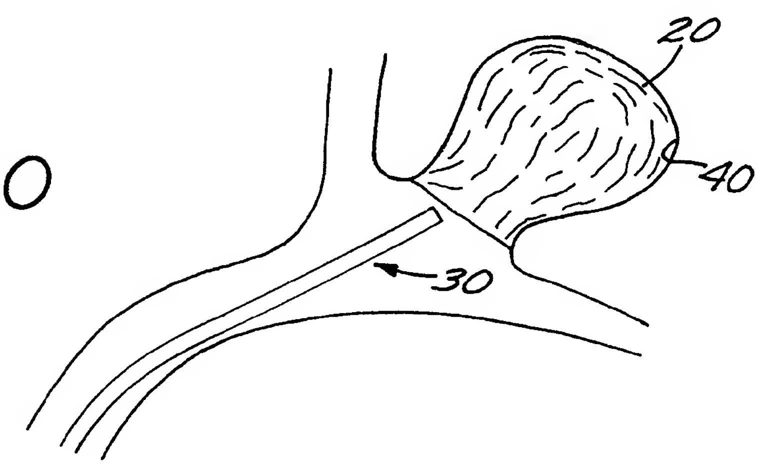


FIG. 10



INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 99/15108

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/12

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	WO 98 04198 A (GREFF RICHARD J ;JONES MICHAEL L (US); MICRO THERAPEUTICS INC (US)) 5 February 1998 (1998-02-05) page 11, line 16 -page 13, line 31; figures 2,6	1-5,7, 25-30 8
X	WO 89 11257 A (AUGSPURGER LYNN L) 30 November 1989 (1989-11-30) page 10, line 2 -page 11, line 22 abstract; figure 5	8-20
A	US 5 554 190 A (DRAENERT KLAUS) 10 September 1996 (1996-09-10) abstract; claim 1; figure 1	8-20
A	EP 0 717 969 A (TARGET THERAPEUTICS INC) 26 June 1996 (1996-06-26) abstract; figures 1,4,5	1,8,25

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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"O" document referring to an oral disclosure, use, exhibition or other means

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"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
28 September 1999	04/10/1999

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Hansen, S

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INTERNATIONAL SEARCH REPORT

Inte ional Application No
PCT/US 99/15108

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 750 585 A (PARK HAESUN ET AL) 12 May 1998 (1998-05-12) abstract ---	1,3,4, 25,28
A	EP 0 664 104 A (MICRO THERAPEUTICS INC) 26 July 1995 (1995-07-26) abstract; figures 13A,15A -----	1,8,25

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Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 99/15108

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 21-24
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Intr 'ional Application No
PCT/US 99/15108

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